

WHAT IS CLAIMED IS:

1. A method of treating a cellular proliferative disease, comprising administering to a mammalian host a pharmaceutical composition comprising:
 - 5 (a) a therapeutically effective amount of liposomal entrapped irinotecan also comprising cardiolipin; and
 - (b) a pharmaceutically acceptable excipient.
- 10 2. The method of claim 1, wherein said mammalian host is a human.
3. The method of claim 1, wherein approximately 3-fold less irinotecan accumulates in cardiac tissue as compared to conventional irinotecan.
- 15 4. The method of claim 3, wherein the area under the irinotecan plasma concentration curve is 200-fold higher than with the conventional irinotecan formulation.
- 20 5. The method of claim 1, wherein said plasma half life is approximately 10-fold greater than with the conventional irinotecan formulation.
6. The method of claim 1, wherein said cardiolipin is selected from the group consisting of natural cardiolipin and synthetic cardiolipin.
- 25 7. The method of claim 1, wherein said liposome bears a negative charge.
8. The method of claim 1, wherein said liposome bears a positive charge.
9. The method of claim 1, wherein at least a portion of said liposome entrapped irinotecan is complexed with cardiolipin.
- 30 10. The method of claim 1, wherein said liposomes are a mixture of multilamellar vesicles and unilamellar vesicles.
- 35 11. A therapeutic composition comprising a liposome entrapped irinotecan wherein said liposome comprises a first liposome forming material comprising cardiolipin and a second liposome forming material.

12. The composition of claim 11, wherein a portion of said cardiolipin is complexed with irinotecan.

5 13. The composition of claim 12 wherein said liposome entrapped irinotecan comprises vesicles having a size of about 5 μm or less.

14. The composition of claim 12 wherein said liposome entrapped irinotecan comprises vesicles having a size of about 1 μm or less.

10 15. The composition of claim 12 wherein liposome entrapped irinotecan comprises vesicles having a size of about 0.5 μm or less.

15 16. The composition of claim 12 wherein said liposome entrapped irinotecan comprises vesicles having a size of about 0.1 μm or less.

17. The composition of claim 11, wherein said second liposome-forming material is a lipid selected from the group consisting of phosphatidyl choline, cholesterol, α -tocopherol, dipalmitoyl phosphatidyl choline and phosphatidyl serine.

20 18. The composition of claim 11, wherein said cardiolipin is selected from the group consisting of natural cardiolipin and synthetic cardiolipin.

25 19. The composition of claim 11, wherein said liposome bears a negative charge.

20. The composition of claim 11, wherein said liposome bears a positive charge.

30 21. The composition of claim 11, wherein said liposome is neutral.

22. The composition of claim 11, wherein said liposome is a mixture of multilamellar vesicles and unilamellar vesicles.

35 23. A method for the treatment of mammalian cancer comprising administering a therapeutically effective amount of the composition of claim 11 to a subject in need thereof.

24. A method of treating a cellular proliferative disease, comprising administering to a mammalian host a pharmaceutical composition comprising:
(a) a therapeutically effective amount of liposomal entrapped camptothecin also comprising cardiolipin, and
5 (b) a pharmaceutically acceptable excipient.

25. The method of claim 24, wherein said mammalian host is a human.

26. The method of claim 24, wherein approximately 3-fold less
10 camptothecin accumulates in cardiac tissue as compared to conventional camptothecin.

27. The method of claim 26, wherein the area under the camptothecin plasma concentration curve is 200-fold higher than with the conventional camptothecin formulation.
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28. The method of claim 24, wherein said plasma half life is approximately 10-fold greater than with the conventional camptothecin formulation.

29. The method of claim 24, wherein said cardiolipin is selected from the
20 group consisting of natural cardiolipin and synthetic cardiolipin.

30. The method of claim 24, wherein said liposome bears a negative charge.

31. The method of claim 24, wherein said liposome bears a positive charge.
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32. The method of claim 24, wherein at least a portion of said liposome entrapped camptothecin is complexed with cardiolipin.

33. The method of claim 24, wherein said liposomes are a mixture of
30 multilamellar vesicles and unilamellar vesicles.

34. A therapeutic composition comprising a liposome entrapped camptothecin wherein said liposome comprises a first liposome forming material comprising cardiolipin and a second liposome forming material.
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35. The composition of claim 34, wherein a portion of said cardiolipin is complexed with camptothecin.

36. The composition of claim 35 wherein said liposome entrapped camptothecin comprises vesicles having a size of about 5 μm or less.

5 37. The composition of claim 35 wherein said liposome entrapped camptothecin comprises vesicles having a size of about 1 μm or less.

38. The composition of claim 35 wherein liposome entrapped camptothecin comprises vesicles having a size of about 0.5 μm or less.

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39. The composition of claim 35 wherein said liposome entrapped camptothecin comprises vesicles having a size of about 0.1 μm or less.

40. The composition of claim 34, wherein said second liposome-forming material is a lipid selected from the group consisting of phosphatidyl choline, cholesterol, α -tocopherol, dipalmitoyl phosphatidyl choline and phosphatidyl serine.

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41. The composition of claim 34, wherein said cardiolipin is selected from the group consisting of natural cardiolipin and synthetic cardiolipin.

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42. The composition of claim 34, wherein said liposome bears a negative charge.

43. The composition of claim 34, wherein said liposome bears a positive charge.

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44. The composition of claim 34, wherein said liposome is neutral.

45. The composition of claim 34, wherein said liposome is a mixture of multilamellar vesicles and unilamellar vesicles.

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46. A method for the treatment of mammalian cancer comprising administering a therapeutically effective amount of the composition of claim 11 to a subject in need thereof.

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